REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 43-47 have been added. Support for these new claims may be found in prior pending claims 1-42. Claims 1-13, 25-26 and 38-39 are withdrawn from consideration and claims 14-24, 27-37 and 40-42 have been canceled. Claims 43-47 are now pending.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claims remain under examination in the application, is presented, with an appropriate defined status identifier.

Rejections under 35 USC §101

The examiner rejected claims 27-37 under 35 USC §101 because the claimed subject matter covered "a use" instead of "a process or method" of treatment. Applicants have canceled claims 27-37 and added new claims 43-47 which are directed to a "method of treatment." Accordingly, applicants respectfully request that the examiner withdraw this rejection.

Rejections under 35 USC §112, first and second paragraphs

The examiner rejected claims 14-19, 22, 24, 27-37 and 40-42 for a lack of enablement, a lack of sufficient written description, and for being indefinite. The examiner has recognized that the claims are enabled for a method of treating inflammatory bowel disease by administering effective amounts of a monoclonal antibody, PM-1 or MR16-1 against the human IL-6 receptor. However, the examiner alleged that the specification does not enable a method of preventing or treating inflammatory bowel disease by administering "all" IL-6 antagonists. Applicants have canceled the rejected claims and added new claims 43-47, which cover a method of treating inflammatory bowel disease by administering an anti-interleukin-6 receptor antibody.

Paragraphs 132-146 and 156-166 describe how the anti-interleukin-6 receptor antibody binds to the IL-6 receptor and thus acts as a therapeutic agent for inflammatory bowel disease. Accordingly, this lack of enablement rejection has been overcome.

In addition, applicant's new claims overcome the examiner's written description rejection because the claims cover an anti-interleukin-6 receptor antibody, which is described in the specification in paragraphs 5, 6, 17, 20, 35-39, 58-65, 99-107, 112, 132-146, and 156-166. Furthermore, with regards to the examiner's rejection of the claims for indefiniteness, the new claims specify that the inflammatory bowel disease is treated with a receptor antibody as suggested by the examiner.

Double Patenting Rejection

The examiner has rejected claims 14-19, 22, 24, 27-37 and 40-42 on the ground of non-statutory obviousness-type double patenting, as being unpatentable over claims 1-4 of U.S. Patent No. 6,723,319 (the "'319" patent). Accordingly, applicants concurrently file herewith a terminal disclaimer with respect to the claims of '319 patent.

Claim Rejections Under 35 USC § 102

The examiner has rejected claims 14-19, 24, 27-32, and 37 as being anticipated by WO 96/38481 (the "'481" reference). Applicants respectfully disagree.

The '481 reference teaches that the blocking of all gp130-related signals is useful for treatment of inflammatory diseases. However, the present invention treats inflammatory bowel diseases through blocking only the IL-6 related signal. As one of ordinary skill in the art would know and as the reference itself states on page 4, lines 23-30, the gp130 molecule plays a role not only in IL-6 signal transduction, but also in the transduction of many other signals, including leukemia inhibitory factor, ciliary neurotrophic factor, oncostatin M and cardiotrophin-1. Accordingly, one of ordinary skill in the art would not conclude that blocking only IL-6 signal transduction would necessarily treat an inflammatory disease.

Furthermore, the '481 reference teaches on page 3, lines 26 to 29, that "gp130 is a portion of the receptor for a number of cytokines that promote the acute phase response (including interleukin 11, leukemia inhibitory factor and oncostatin M), inhibition of that response with an antibody may well be employed as an anti-inflammatory agent, since the acute phase response is part of the inflammatory process. " This description suggests that since gp130 mediates transduction of many signals, the gp130 can be a target of inhibition of acute phase response, in other words, the description suggests that an entity which does not relate to transduction of many signals cannot be a target of inhibition.

An Information Disclosure Statement (IDS) under 38 C.F.R. § 1.56 is submitted herewith to disclose a non-patent reference, British Journal of Hematology, 1996, Vol. 95, pp. 443-541 by the authors of the '481 citation, in which the following is described:

> A number of other IL-6 like cytokines including leukemia inhibitory factor, oncostatin M, ciliary neurotrophic factor and interleukin 11 also mediate similar biological effects including induction of the acute-phase response. Evidence for their functional redundancy is provided by studies of IL-6-/- knockout mice where lipopolysaccharide (LPS) treatment still results in slight elevation of acute-phase proteins.
>
> This apparent functional redundancy can be explained since their cellular signals are all transduced via common receptor β chain subunit known as gp130 (CD130). As gp130-/- knockout mice are not viable 6-8 days after gestation, blockage of gp130 signal transduction may provide the only suitable model where the biological effects of the entire IL-6 family could be inhibited in vivo.

As can be seen from the above, it is clear that a person of ordinary skill in the art would consider it essential to treat inflammatory bowel diseases through blocking the transduction of all gp130-related signals, and would not conclude that blocking the transduction of only the IL-6-related signal would effectively treat inflammatory bowel diseases.

Accordingly, applicants submit that the present invention is inventive over the cited reference.

Claim Rejections Under 35 USC § 103(a)

The examiner has rejected claims 22, 35, 40-42 as being unpatentable over WO 96/38481 in view of Queen et al. (U.S. Patent No. 5,530,101). Applicants respectfully disagree.

The Queen reference teaches the production of antibody fragments, including the FAB fragment and the production of chimeric antibodies and the humanization of monoclonal antibodies as well as designing a humanized antibody that retains affinity for its antigen. However, nothing in this reference suggests using an antibody fragment of an anti-interleukin-6 receptor to treat inflammatory bowel disease. As explained above in response to the examiner's 102(b) rejection, the '481 reference also does not teach, suggest or motivate one of ordinary skill in the art to treat inflammatory bowel disease through blocking the IL-6 receptor alone. Accordingly, based on both the arguments set forth above and on the scope of the Queen reference, applicants request the examiner withdraw this rejection and allow the new claims 43-47.

Conclusion

In view of the foregoing remarks, Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application, as amended, is respectfully requested.

The examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or

credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

A Petition for three one-month extensions of time under 37 C.F.R. §1.136(a), a fee under 37 C.F.R. § 1.17(p) for an IDS, and a Fee for a Statutory Disclaimer under 37 C.F.R. §1.20(d) are enclosed herewith.

Respectfully submitted,

Date August 2, 2007 By _____

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5569
Facsimile: (202) 672-5399

Stephen B. Maebius
Attorney for Applicant
Registration No. 35,264

HCW/SBM/ARSC:kdm